REMARKS

The undersigned, on behalf of the Applicants, would like to express appreciation to Examiner Hui for the telephone interview granted on April 23, 2003. The interview was helpful in clarifying some of the issues raised in the Office Action of January 28, 2003.

Claims 1 to 26 are in the application.

Claims 22, 23 and 26 stand objected to on the grounds that the use of the term "GDO", "MCT/GDO" and "GDO/GMO" are improper.

Claims 1-26 stand rejected under 35 USC 103(a) as being obvious over Romines et al (USPN 5 852 195) and Suzuki et al (USPN 5 693 337), in view of Remington (Remington's Pharmaceutical Science, 18th Ed., Pages 1172, 1286, 1316) and Lyons (USPN 5 693 337).

THE OBJECTION TO CLAIMS 22, 23 AND 26

Claims 22, 23 and 26 have been amended by replacing "GDO/GMO" with ---Diglyceride/Monoglyceride--- in Claims 22 and 26; "GDO" with ---Diglyceride--- and "MCT/GDO" with ---Triglyceride/Diglyceride--- in Claim 23. The meaning of GDO can be found on page 5, lines 18-21, of the specification; the meaning of GMO on page 5, lines 25-28 of the specification; and the meaning of MCT on page 5, lines 33-35, of the specification. Hence, the insertion of the terms Diglyceride, Monoglyceride and Triglyceride into Claims 22, 23 and 26 does not constitute new matter.

THE REJECTION OF CLAIMS 1 TO 26 UNDER 35 USC 103(a)
AS BEING UNPATENTABLE OVER
ROMINES ET AL (USPN 5 852 195) AND
SUZUKI ET AL (USPN 5 693 337)
IN VIEW OF REMINGTON (REMINGTON'S PHARMACEUTICAL SCIENCE,
18TH Ed., Page 1172, 1286, 1316 and 1317)
AND LYONS (USPN 5 616 342)

Applicants traverse this rejection on the grounds that the Examiner has not established a prima facie case of obviousness.

Claim 1 defines a submicron lipid emulsion pharmaceutical composition comprising (a) a therapeutically effective amount of a pyranone compound of Formula I; (b) an oil component selected from the group consisting of mono-, di-, triglyceride or a mixture thereof wherein the monoglyceride and diglyceride are mono- and di-unsaturated fatty acid esters of glycerol having sixteen to twenty-two carbon atom chain length, wherein triglyceride is a saturated fatty acid of glycerol having six to twelve carbon atom chain length; (c) an emulsifying agent consisting of lecithin; and (d) a liquid phase comprising one or more pharmaceutically acceptable solvents, wherein said pharmaceutical composition does not contain either an amino acid, citric acid or a pharmaceutically acceptable salt of citric acid. The amendment of Claim 1 to recite that the pharmaceutical composition does not contain either an amino acid, citric acid or a pharmaceutically acceptable salt of citric acid finds support in Examples 1-5 since none of the pharmaceutical compositions described in Examples 1-5 contain either an amino acid or citric acid.

The primary references, Romines et al and Suzuki et al, do not teach or suggest the pharmaceutical composition of Claim 1 and the Remington and Lyons reference do not cure the defects of the primary reference. Romines simply discloses the compound of Formula I. It does not teach or suggest an

emulsion or any other components of the claimed composition. Suzuki et al discloses a liquid emulsion that requires the presence of (a) a drug, (b) an oil component (c) lecithin, (d) water, (e) an amino acid and (f) citric acid or a pharmaceutically acceptable salt thereof. Suzuki et al states, in Column 3, lines 47-49,

> It is an essential requirement in the present invention to simultaneously use citric acid and at least one of the foregoing amino acids. (emphasis added)

Present Claim 1 excludes the presence of an amino acid, citric acid or a pharmaceutically acceptable salt of citric acid. Hence, Suzuki et al teaches away from any suggestion to modify their composition by excluding amino acids and citric acid since such modification would render their composition inoperable.

Claims 2-21 further define the pharmaceutical composition of Claim 1 by adding further limitations thereto. Therefore, Claims 2-21 are patentably distinguishable over the cited prior art for the reason that Claim 1 is, and are further patentably distinguishable thereover because of the additional limitations recited therein.

It should be noted that Claim 5 has been amended to correct a typographical error. Specifically, the word --is-- was inserted in the second line between the words "lecithin" and "a".

Claims 22-26 are patentably distinguishable over the combination of the cited references for the reasons that Claim 1 is and because of the additional limitations recited in them. For Example, Claims 22, 23 and 26 recite specific types, specific amounts and specific ratios of components. Claim 24 recites a specific ratio of diglyceride to monoglyceride (8:2). Claim 25 limits the pharmaceutical composition of Claim 24 to an oral or parenteral composition.

EXAMINER'S RESPONSE TO APPLICANTS' ARGUMENT MADE IN THE RESPONSE OF NOVEMBER 4, 2002

In responding to Applicants' argument that Suzuki et al requires the presence of citric acid in their emulsion, the Examiner asserts in the paragraph bridging pages 5 and 6,

> Applicant argues that Suzuki et al requires the presence of citric acid in its emulsion. Note that the instant claims contain the open transitional phrase "comprising" which does not exclude the presence of other components, e.g. citric acid.

However, the Examiner's attention is directed to Claims 22-26. None of these claims, which were presented in Applicants' Response of November 4, 2002, read on compositions that contain either an amino acid, citric acid or a pharmaceutically acceptable salt of citric acid. Present Claims 1-21 all define a composition that does not contain either an amino acid, citric acid or a pharmaceutically acceptable salt of citric acid.

In view of the amendments and arguments contained in this Response, withdrawal of the objection and rejection and expeditious passage of this application to issue is respectfully solicited.

Respectfully submitted,

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